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14. ABSTRACT

One of the hallmark features of Posttraumatic Stress Disorder (PTSD) is a marked increased in physical arousal (i.e., increased heart rate, muscle tension, etc.) when recalling a trauma-related memory. In this manner, a treatment that decreased the hyper-arousal of a traumatic memory to less-impairing levels may do well in allowing an individual with PTSD to return to his or her daily life. However, there is an imbalance at the heart of combat PTSD-related research: in over three decades' worth of research on combat stress PTSD physiology, only 3% (66 out of 1,985 participants) of the Veterans studied were women. This paucity of research is in the face of the fact that PTSD is twice as likely to occur in women. Our research investigates a novel method of reducing the hyper-arousal associated with combat memories in Female Operation Iraqi Freedom and Operation Enduring Freedom Veterans with PTSD. Our study compares Female Veterans who take propranolol after a combat memory to both Female Veterans who take a non-active placebo pill after a combat memory and those who take propranolol after a non-combat memory (to make sure that propranolol doesn't have a general effect on physical reactions). All participants in our study are tested during the early follicular phase of the menstrual cycle, a time in which levels of estrogen are low. Dr. Aikins has left Yale University and accepted a position at The Wayne State University and VA Detroit Healthcare System. The award was successfully transferred in the Fall semester of 2013. IRB and HRPO amendments were approved and recruitment has begun.

15. SUBJECT TERMS

PTSD treatment, Women's Health, memory reconsolidation

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INTRODUCTION

In this study, we investigated a method for blocking memory reconsolidation in three groups of female Veterans of either Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF) with PTSD: 1) Individuals (n=20) who received propranolol following recall of a traumatic memory (Propranolol-trauma); 2) Individuals (n=20) who received a placebo following recall of a traumatic memory (Placebo-trauma), and; 3) Individuals (n=20) who received propranolol following recall of an affective neutral memory (Propranolol-neutral). Memory recall was to be psychophysiologically assessed by measuring facial corrugator electromyography (EMG), skin conductance, blood pressure and cardiovascular inter-beat interval responses immediately prior and four weeks following medication administration. We predicted a significant drop in physiological reactivity to Veterans' trauma memories and PTSD intrusive symptoms in the Propranolol-trauma group. Despite several large-scale recruitment efforts, we were unable to successfully recruit female Veterans for this protocol.

BODY

The work accomplished in the last 12 months of the award focused on recruitment. We contacted Mason, Inc., a Connecticut-based advertising firm with expertise in recruitment for clinical trials. Using funds from Dr. Aikins' VA affiliation, a small campaign was developed that would directly reach Female OIF/OEF Veterans in Connecticut. The materials were then approved by the VA Connecticut Human Subjects Safety committee, Yale IRB, and HRPO. Our goal was to reach an additional 1,300 Female Veterans.

Using both mail and email methods and the creation of a micro website recruitment system, 1,300 individuals were contacted. Approximately 200 responses were received from individuals who had no relationship with the military and did not wish to be contacted in the future. Mason, Inc. had indictaed a potential 5% error rate in the methodology that would generate the female Veteran contact information and the 200 responses fell within that range.

As of September 2012, Dr. Aikins left Yale University for a tenured faculty position at The Wayne State University and VA Detroit Healthcare system. A new clinical laboratory was to be built for him at VA Detroit. The VA Detroit has both a PTSD treatment team and a Military Sexual Trauma program with active caseloads and has agreed to refer Female Veterans to the protocol. Further, Wayne State University has a sizeable returning education program for OEF/OIF/OND Veterans.

In 2013, Dr. Aikins transferred the award to Wayne State. He obtained Wayne State IRB approval of the study and HRPO approved the amendment to move the study to Wayne. Laboratory materials for this study was purchased and study personnel have been hired. Recruitment has begun.

KEY RESEARCH ACCOMPLISHMENTS

- Award transferred to new institution.
- Study opened at Wayne State University.

REPORTABLE OUTCOMES

Female OIF/OEF-era Veterans with PTSD are extremely reluctant to engage in either clinical services or clinical trials. To date, we have screened 39 Female Veterans and enrolled 14 into the clinical trial. Notably, none of the 14 participants completed the trial. Importantly, 20% of our sample was excluded from the trial because of a low resting heart rate and blood pressure. This is consistent with our experience with Male Veterans and presents an important limitation to the consideration of propranolol as a PTSD treatment. Further, illicit drug use and patient drop-out were the top two patient-factors for Female Veterans to not complete the trial. Our profile of participant engagement parallels that found with those Female Veterans who enroll in Psychiatric Services at the VA Connecticut Healthcare System. Using VA funds available to Dr. Aikins, a new recruitment advertising campaign was designed for outreach into the OIF/OEF Female Veterans community in Connecticut. This campaign failed to increase recruitment.

CONCLUSION

This research addresses important issues regarding the treatment of Female Veterans with PTSD. However, the ability to engage this community has proved to be much more difficult than originally anticipated. Dr. Aikins has restarted the award at his new institution.

REFERENCES

N/A